

February 24, 1977

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Dear Don,

I appreciate your invitation to participate in the meeting convened to discuss NIH and the Federal Interagency committee's activities concerning recombinant DNA research. I had hoped to attend but the urgency and immutability of several deadlines made it impossible for me to leave Stanford for those two days. Nevertheless, I do want to share my thoughts, and particularly my concerns, about the tone and substance of current discussions on recombinant DNA research.

As I see it, the principal criticisms raised against the NIH guidelines fall into three classes. The first includes disagreements on the scientific issues, e.g., the risk factors assigned to various experiments, the reliability of the specified forms of physical and biological containment or the use of E. coli K12, etc.; the second focuses on implementation of the guidelines, e.g., the failure to include research performed in the industrial sector and other non-government funded laboratories, the perception that compliance with the guidelines seems to be voluntary and unmonitored and the apparent absence of legal sanctions; the third addresses the failure of the recombinant DNA guidelines to deal with biological warfare, terrorist activities, genetic manipulation of humans and other suspected malevolent activities.

I understood that the February 19th meeting was to deal with the second group of criticisms and to discuss the policy alternatives that address these matters. Consequently, I'll not comment, except indirectly, on the scientific issues; particularly, since further debate of these points seems to be futile and unrewarding without new experimental data. The questions of gangsterism, clandestine military experiments or other forms of surreptitious misuse are just too complex to be dealt with by means that must also apply to serious scientists. Besides, I have nothing but intuition and bias to offer on that score.

Let me speak my mind, then, on the issue of implementation. Unquestionably, there is a need to make all recombinant DNA research, wherever it's being done and whoever is doing it, follow the guidelines. It is blatant sophistry and mischievous to condemn the guidelines for failing in what they were never intended nor could accomplish, namely, application to the industrial and non-government-funded research community. What the guidelines did achieve was to bring more than 90% of the research that was

in progress, or about to be undertaken in this country, under control; moreover, they catalysed corresponding actions in virtually every nation carrying out similar work. Having accomplished that, it's reasonable to consider how to make the next step: to find ways and means to extend the jurisdiction of the guidelines to all recombinant DNA activities in this country.

I believe we should be looking for and insisting upon a mechanism that is effective and minimally disruptive to research efforts. In my view, the draft bill introduced into the New York State Legislature, the one developed by the California Department of Health for submission to the State Assembly and the Bumpers' "DNA Research Act of 1977" are unwise, unnecessary and potentially more hazardous to the health and welfare of our nation than the recombinant DNA experiments themselves.

I cannot imagine how the promulgation of counterproductive measures that threaten imprisonment and huge fines, that dissipate time and energy doing the endless paperwork needed to obtain yearly licensing and satisfying inspectors, that waste precious funds seeking the unattainable absolute security and that ~~would~~ drag crackpots to sue investigators and universities for every imagined ailment or mishap can be viewed as a reasoned response to something which has never been shown to produce any untoward effects. The expenditures that will be needed to support the new bureaucracy in Washington, in the states and in the universities will further erode the already limited support for research in biomedical science.

I believe that such legislation will have a devastating effect on young people, particularly; it may well deter our best young scientists from entering such a treacherous morass. It all makes me fear for the future of biomedical research. One need only recall how the stupidities and bureaucratic machinations of Lysenkoism blocked Soviet biologists from entering the modern era, to speculate about whether we are dooming the next generation of genetic research in this country.

We should consider carefully whose and what purpose will be served by such legislation. I am astonished at how the initially serious effort to deal with the highly conjectural risks posed by some recombinant DNA experiments has degenerated to the point where a presumably responsible public official could rise in a public body and make such uninformed and irresponsible assertions as "we are engaging pell mell in one of the most dangerous kinds of research ever undertaken in this country". It disturbs me even more to read equally outrageous and unjustified statements from so-called distinguished scientists "that the spreading of experimental cancer may be confidently expected" from recombinant DNA research. Can we be surprised, therefore, that a presumably objective science reporter can wonder in print if the world, having barely survived "Three Narrow Escapes", can be certain that "all biologists in the future will always act with as much intelligence and restraint". Where is the cool and dispassionate analysis of the issues that confound us? Must the assertions that the sky will fall force us to debate only how thick the concrete walls must be on our shelters, or can we still speculate upon whether the sky might fall at all?

Don, my energies and intellect are directed to the creative pursuits of science. I think I do that pretty well. But I have no special knowledge, talent or inclination to deal with those who see the recombinant DNA issue as a game, an exercise in practical politics, or as an opportunity for personal advantage. My instincts tell me we are in deep trouble if we accept Bumpers' vision of how research can and should be conducted. There is clearly as much need for intelligence and ingenuity in finding the mechanisms to assure that the research can go forward, as is needed for achieving its benefits at the laboratory bench. Surely some means can be found to bring industrial research and development and the few non-government funded activities into compliance with the guidelines without doing irreparable damage to what is generally acknowledged to be the finest biomedical research system in the world.

Why couldn't we aim for legislation or executive orders that would permit a government agency, e.g., the Department of Commerce or HEW, to oversee the guidelines for industrial organizations? Couldn't each firm or laboratory be required to organize an institutional Recombinant DNA Review Board (containing individuals from all levels of the company and community) and to require them to file with the relevant Department detailed MUA's about the design, containment, etc., of all experiments or developmental work? These could be a prerequisite to patent applications or for obtaining government contracts on any products or procedures developed using recombinant DNA methods. Such sanctions would probably be as effective in inhibiting violations by industrial concerns as threats to terminate research grants and contracts discourage noncompliance in universities. I believe the mechanisms mandated for universities and research institutes and monitored through NIH can and will function effectively even though it is cumbersome. Threats of imprisonment, fines or legal suits will not increase the safety of the work--in the end only the responsibility of the investigators will ensure that.

I don't know if venting my feelings in this way has been useful to you. They reflect my discouraged and somewhat pessimistic mood of the present. I am also deeply concerned about this being the opening bell for a war on science, that in accepting legislative oversight of the means and goals of research we shall be creating even more fearsome problems for other areas of investigation in the future.

I wish I could have attended the meeting last weekend as I'm sure I would have profited from the comments and the give-and-take discussions with the others.

Good luck in your efforts.

Very sincerely yours,

Paul Berg

PB/sc  
cc: Joseph G. Perpich